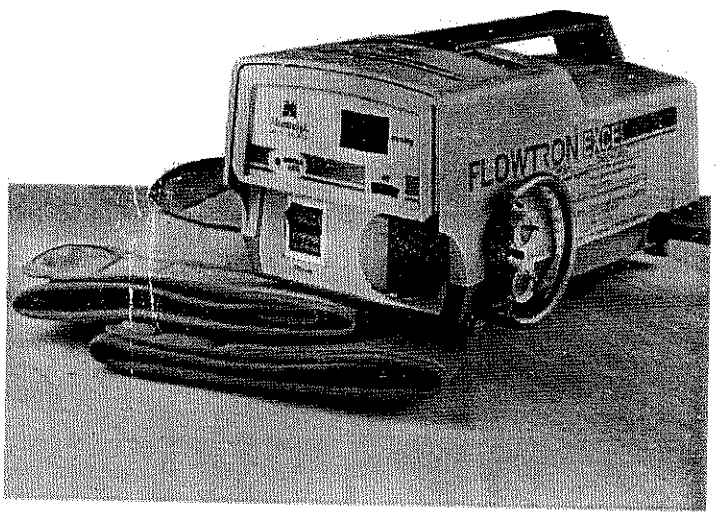
Huntleigh
HEALTHCARE

FLOWTRON® EXCEL



Operating Instructions • Model AC550

External Pneumatic Compression System for DVT Prophlaxis

Contents

Description and Operating Principle 1

Cautions and Contraindications 3

Cautions 3

Contraindications 3

System Set Up 4

Garment Application 5

To Use One Garment 5

Pump Operation 6

Pre-Use Check 6

Operation 6

Pressure Adjustment 7

Pressure Output Check 7

Resetting the Output Pressure 7

System Calibration Check 7

Troubleshooting 8

Alarm Cancel 9

Corrective Action Check (when using On/Off Reset) 9

Fuse Replacement 9

Warranty and Service 10

Warranty 10

Service 11

Cleaning Instructions 12

Garment Information 13

Technical Data 14

General Safety

Before you connect the system pump to a mains socket, read carefully all the installation instructions in Section 3 - System Set Up. The system has been designed to comply with regulatory safety standards including:

- UL60601-1 First Edition
- CAN/CSA C22.2 No. 601-1-M90

Safety Warnings

- Electrical equipment may be hazardous if misused. The pump's case back should only be removed by authorised technical personnel.
- Do not use the pump in the presence of flammable gases such as anaesthetic agents.

Caution

Electromagnetic compatibility (EMC). This product complies with the requirements of applicable EMC Standards. The use of accessories not specified by the manufacturer may result in increased emissions by, or decreased immunity of, the equipment, affecting its performance

Precautions

For your own safety and the safety of the equipment, always take the following precautions:

- Regularly check the system when in use, for pump operation and garment fit.
- Keep the pump away from sources of liquids and do not immerse in water.
- Do not expose the system, especially the garments, to naked flames, such as cigarettes etc.
- Do not store the system in direct sunlight.
- Switch off the electrical supply to the pump by disconnecting the pump from the mains socket before cleaning and inspection.
- Do not use hypercarbonate or phenolic based cleaning solutions.
- Ensure the system is clean and dry prior to storage.

Only the pump and garment combination as indicated by Huntleigh Healthcare should be used. The correct function of the product cannot be guaranteed if the incorrect pump/garment combinations are used.

1. Description and Operating Principle

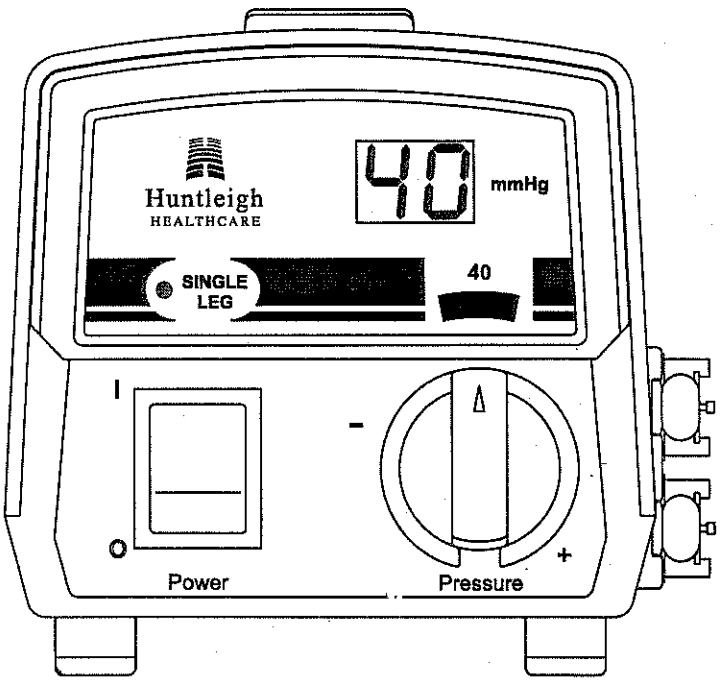
Flowtron® Excel is a non-invasive prophylaxis system for reducing the incidence of deep vein thrombosis (DVT). The application of intermittent pneumatic compression has two effects:

1. Augments venous blood flow velocity, thereby reducing stasis.
2. Enhances fibrinolytic activity to reduce the risk of early clot formation.

The **Flowtron Excel** system consists of a pump and a pair of calf or thigh length, single patient use garments. The pump provides intermittent cycles of compressed air which alternately inflate the single-chambered air garments. The compression applied on the extremity augments venous blood flow velocity and stimulates fibrinolysis.

The pump operates on a 60-second automatically timed cycle consisting of approximately 12 seconds of inflation followed by approximately 48 seconds of deflation.

The **Flowtron Excel** system may be used on patients at risk of developing deep vein thrombosis and in conjunction with systemic interventions (e.g. anticoagulation drugs.) for the high risk patient.



Flowtron Excel Pump Front View

2. Cautions and Contraindications

Cautions

1. Proper application and connection to the pump is essential.
2. Garments should be removed if the patient experiences tingling, numbness, or pain.
3. Interruption of external pneumatic compression for a substantial length of time is discouraged.

Contraindications

Flowtron Excel should NOT be used in the following conditions:

1. Severe arteriosclerosis or other ischemic vascular diseases.
2. Known or suspected acute deep vein thrombosis.
3. Severe congestive cardiac failure.
4. Any local condition in which garments wouls interfere, for example:
   - Gangrene
   - Untreated, infected leg wounds
   - Recent skin graft
   - Dermatitis

3. System Set Up

The system is easy to set up:

1. Remove the pump and tubing from the carton.
2. Plug pump into electric outlet - DO NOT switch on at this time.
3. Insert tubing assembly into the snap-lock connectors at the side of the pump. Press firmly until a sharp 'click' is heard. Pull lightly to confirm proper connection.

WARNING

DO NOT use pump in the presence of flammable anesthetic gases.

4. Garment Application

1. Check that the power switch on the pump is OFF. Remove the garments from the packaging and unfold.
2. Place the back of the patient's leg in the centre section of the garment with the connector tubing pointing towards the foot.
3. Starting with the side that does not have the Velcro®[1] tabs, wrap securely against the leg. While holding the garment snugly against the leg, wrap the taps over the top. Ensure that the garments are fitted snugly and are not 'wrinkled' or 'tucked'. The connector tubing should be pointing towards the patient's heel.
4. Snap-lock the garment connector to the tubing assembly. Ensure that a sharp 'click' is heard. Pull lightly to confirm a proper connection.
5. To disconnect the garments from the tubing, press the snap-lock connector and pull apart.

IMPORTANT

If garments are not applied snugly, a Lo pump alarm may result. To correct the alarm, simply rewrap the garment snugly.

To Use One Garment

To use only one garment, connect a single tube to either connector. The snap-lock connectors on the pump are self-sealing and, unlike other systems, DO NOT require the unused garment to be attached.

Press the **Single Leg** button to prevent the alarm system incorrectly indicating a fault. The system responds with a 'beep' and the LED on the button illuminates. If the **Single Leg** button is pressed by mistake with two garments connected, the system will reset itself to normal after two cycles.

1. Velcro® is a registered trademark of VELCRO USA Inc.

5. Pump Operation

Pre-Use Check

Before using the **Flowtron Excel** system on the patient, ensure that:

- The pump has been set at 40 mmHg (or the pressure prescribed by the physician).
- Garments have been applied to patient's legs. correctly, snugly and without wrinkles.
- There are no kinks in the tubing.
- The pump is connected to an electrical outlet.
- All tubing connections are secure.

Operation

Turn the power switch ON which will illuminate green. The pump performs a two-second self test cycle where the display, LED's and alarm are tested. The compressor then proceeds directly to the inflation cycle.

The garments will inflate alternately. The first garment inflates for approximately 12 seconds and is deflated for approximately 48 seconds.

The second garment inflates 30 seconds after the inflation of the first garment and follows the same inflation/deflation cycle.

Verify that the display is indicating the desired output pressure. Refer to section 6 - **Pressure Adjustment** for specific pressure setting instructions.

6. Pressure Adjustment

The pressure control mechanism is located on the front of the pump and ranges from 30-60mmHg. The pressure exerted by the garments on the leg can be adjusted by turning this knob. Turning the knob clockwise increases the pressure; counterclockwise decreases the pressure.

☞ *The recommended pressure setting is 40 mmHg, or the pressure prescribed by the physician.*

The **Flowtron Excel** pump pressure monitoring system is independent of the pressure control and delivery system, providing added reliability and safety. The digital display indicates the actual pressure that is delivered to the garments, and furnishes immediate and continuous feedback regarding pump performance.

The pressure display is used for the following functions:

Pressure Output Check

After turning the pump on, check that the pressure display is showing the desired output pressure when the garments are inflated. Visually recheck the display at regular intervals.

Resetting the Output Pressure

Rotate the pressure control knob during the active inflation period until the required pressure is displayed.

System Calibration Check

To confirm the calibration accuracy of the pressure control and display, perform the following check each time the pump is turned on.

During normal operation when the display reads 40, the pointer on the pressure control knob should be located somewhere within the 40 mmHg arc on the front panel. If the pointer falls outside of this arc, the pump should not be used and referred to service for recalibration.

7. Troubleshooting

The **Flowtron Excel** system features an audible and visual alarm. If a problem occurs, the system will sense the fault and briefly flash a message on the display.

If the same fault continues for successive inflations, the audible alarm will sound and a flashing message will remain on the display until corrective action is completed.

The exception to this is an F fault which will alarm immediately.

Display	Problem	Corrective Action
Lo	1. Loose garment fitting. 2. Hose disconnected at garment. 3. Garment leak. 4. Low pressure.	1. Rewrap snugly. 2. Check the hose connection at garment end. 3. Check garment and replace if faulty. 4. Refer to service.
HI	1. Hose kinked causing a blocked tube. 2. Hose disconnected at pump. 3. Single garment attached without pressing "single leg" button.	1. Check hoses for kinks or obstructions. 2. Check the hose connection at pump outlet. 3. Press 'single leg' button, if only one garment to be used.
F	Pump failure.	DO NOT USE PUMP. Refer to service.

In the unlikely event of a display electronics failure, the red LED on the top panel will rapidly flash (approximately four times a second). **Do not use the pump : refer to service.**

Alarm Cancel

After a fault has been corrected, the alarm can be cancelled by two methods:

1. Switch the pump off, then on again, using the on/off switch.
2. Allow the pump to run until it senses a normal inflation; it will then reset itself.

Corrective Action Check (when using On/Off Reset)

To confirm that the fault has corrected, watch the display for about one minute. If everything is normal, there will be no HI or Lo message flashing during that time.

Fuse Replacement

If the system fails to operate when plugged in and switched on, the fuse on the underside of the pump should be checked. To do this, disconnect the pump from the main power supply and remove fuse holder cap using a suitable screwdriver.

IMPORTANT

To protect against fire hazard, replace blown fuse with identical type and rating - F500mA 250V (0.5 Amp 250V Quick Blow). If the fuse blows again, refer the pump for service.

8. Warranty and Service

Warranty

All Huntleigh Healthcare products shall comform to applicable specifications in effect from the invoice date to the end of the warranty period, and Huntleigh Healthcare reserves the right to change such specifications at any time with or without notice. The warranty period for Huntleigh Healthcare Products shall be as follows calculated from the date of invoice:

a. Intermittent Compression Pumps: one year parts and labor.

b. Single patient use garments have no warranty period, but Huntleigh Healthcare warrants that the Products meet the then current specifications as the date of receipt.

Huntleigh Healthcare's sole liability to the Customer for nonconformity of any Products to the specifications therefore, for any claim arising out of or in any way connected with the manufacture, sale, handling or use of the Products, or for any other reasons, shall be, at Huntleigh Healthcare's sole option, limited to (i) the refund of the full purchase price for such Products, plus the invoice shipping charges, or (ii) replacement thereof, free of change to Customer, with Products conforming to the then current specifications, thereof. The parties agree that these remedies shall be exclusive. Huntleigh Healthcare, AND ITS AFFILIATES, SHALL HAVE NO LIABILITY FOR INCIDENTAL OR CONSEQUENTIAL DAMAGES OF ANY KIND OR, EXCEPT AS PROVIDED ABOVE, FOR ANY CAUSE ARISING OUT OF OR IN ANY WAY CONNECTED WITH THE MANUFACTURE, SALE, HANDLING OR USE OF SUCH PRODUCTS. EXCEPT AS SPECIFICALLY SET FORTH IN THIS PARAGRAPH, THERE ARE NO EXPRESS OR IMPLIED WARRANTIES, INCLUDING THE WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, AND THE FOREGOING PROVISIONS OF THIS PARAGRAPH ARE IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED.

Customer is solely responsible for the proper use of the Products. Huntleigh Healthcare Products should not be used in conjunction with those of any other manufacturers.

Service

The **Flowtron Excel** pump should be routinely inspected (not less than once a year) by a qualified biomedical service technician to assure proper operation of the pump and garment system. Inspection should verify that pressure output and timing cycle are within listed specifications and that the audible and visual alarms function. The **Flowtron Excel** pump should receive annual preventative maintenance.

All required servicing should be performed by Huntleigh Healthcare service personnel.

Service Department
Huntleigh Healthcare L.L.C.
40 Christopher Way
Eatontown, NJ 07724-3327

Telephone : 1-800-223-1218
Fax: 1-732-446-1938

9. Cleaning Instructions

The pump casing is made from ABS plastic and should be cleaned using a soft cloth dampened with a mild detergent.

The pump can be disinfected by wiping down with an EPA-approved, hospital grade disinfectant, as per an appropriate protocol determined by the customer to be valid.

However, using certain chemicals and cleaners will cause severe damage to the pump.

- Never use phenolic, hypocarbonate based disinfectants containing cationic surfactants, ammonia-based compounds, or antiseptic solutions such as Steriscol or Hibiscrub.
- Do not spray cleaning solutions directly onto the pump.
- The pump cannot be sterilized.

All garments are single patient use. Cleaning and reuse of the garments is not recommended.

10. Garment Information

Code	Description	Per Case
AC550	Flowtron Excel Pump with tubing Assembly.	1 each
DVT10	Standard Calf Garment (up to 17" calf circumference).	10 pair
DVT10(S)	Sterile Standard Calf Garment.	10 pair
DVT20	Large Calf Garment (up to 23" calf circumference).	5 each
DVT30	Standard Thigh Garment (up to 28" thigh cirumference).	10 pair
DVT30(S)	Sterile Standard Thigh Garment.	10 pair
DVT40	Large Thigh Garment (up to 35" thigh cirumference).	5 each
L550	Connector Tubing (60" length)	5 pair
L552	Connector Tubing (120" length)	5 pair

To order, contact:

Huntleigh Healthcare L.L.C.
40 Christopher Way
Eatontown, NJ 07724-3327

Telephone: 1-800-223-1218

11. Technical Data

Pump Model No.:	**247001**
Size:	5¼" x 6" x 10¾ inches(133 x 152 x 275 mm)
Weight:	6lbs (2.7 kg)
Pressure Range:	30-60 mmHg
Indicators:	2-digit 7-segment red LED that indicates: - garment pressure in 5 mmHg steps - fault conditions (*HI*.*Lo*.*F*) Single garment amber LED. Power on: green illuminated switch and green LED on top panel. Fault: red LED on top panel.
Cycle:	60 seconds total 12 seconds inflation 48 seconds deflation
Rated Voltage:	120 V
Rated Frequency:	60 Hz
Rated Input Power:	26 V A
Fuse Rating:	F500mAH 250V
Protection Class:	Class I
Equipment Symbols:	Type BF. Not protected against ingress of water. Refer to user manual **SN:** Serial number **Ref:** Model number Alternating Current **O** (Off) Power disconnected from mains supply. **I** (On) Power connected to mains supply. Fuse
Rated for:	Continuous consumption

North American Electrical Safety Standards

Tested to:	UL60601-1 First Edition Classified by Underwriters Laboritories Inc.® with respect to electric shock, fire and mechanical hazards only in accordance with UL60601-1 UL Control Code: 25EA.
	CAN/CSA C22.2 No. 601-1-M90 Classified by Underwriters Laboritories Inc.® in Canada with respect to electric shock, fire and mechanical hazards only in accordance with CAN/CSA C22.2 No. 601.1-M90, UL Control Code: 25EA.

Environmental Conditions

Operating

Temperature Range:	+50°F to +104°F (+10°C to +40°C)
Relative humidity:	30% to 75%
Atmospheric pressure	700hPa to 1060 hPa

Storage

Storage temperature range:	-40°F to +158°F (-40°C to +70°C)
Relative humidity:	10% to 100% (non-condensing)
Atmospheric pressure:	500 hPa to 1060 hPa

Huntleigh
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